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## UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: ESZOPICLONE PATENT LITIGATION

SUNOVION PHARMACEUTICALS INC.,

Plaintiff,

٧.

TEVA PHARMACEUTICALS USA, INC. et al.,

Defendants.

Civil Action No. 09-1302 (DMC) (MF)

(Filed Electronically)

## CONSENT JUDGMENT AND DISMISSAL ORDER

This action for patent infringement (the "Litigation") has been brought by Plaintiff Sunovion Pharmaceuticals Inc. ("Sunovion") against Defendant Teva Pharmaceuticals USA, Inc. ("Teva") for infringement of United States Patent Nos. 6,444,273, 6,319,926, 6,864,257, and 7,381,724 (collectively, the "Sunovion Patents"). Sunovion's commencement of the Litigation was based on its receipt of notice from Teva that Teva had filed ANDA No. 91-169 with the United States Food and Drug Administration containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the Sunovion Patents and seeking approval to market generic versions of 1, 2, and 3 milligram tablets of eszopiclone.

Sunovion and Teva have agreed to enter into a good faith final settlement agreement regarding this Litigation on the expectation and belief that this would eliminate the substantial litigation costs that would otherwise be incurred by both Sunovion and Teva during the Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This reasonable final settlement will afford Sunovion and Teva the procompetitive opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Litigation, to the benefit of the parties and consumers alike, such as by investing more money in pharmaceutical research and development.

Each of Sunovion and Teva acknowledge there is significant risk to each of them associated with the continued prosecution of this Litigation and have consented to entry of this Consent Judgment and Dismissal Order through a final settlement as reflected herein. The Court, upon the consent and request of Sunovion and Teva, hereby acknowledges the following Consent Judgment and, upon due consideration, issues the following Dismissal Order.

Sunovion and Teva now consent to this Consent Judgment and Dismissal Order and IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

- 1. Subject matter jurisdiction, personal jurisdiction, and venue are all proper in this Court.
- 2. In this Litigation, Sunovion has charged Teva with infringement of the Sunovion Patents in connection with Teva's submission of Abbreviated New Drug Application ("ANDA") No. 91-169 directed to generic tablets containing 1, 2, and 3 milligrams of eszopiclone per tablet to the U.S. Food and Drug Administration ("FDA").
- 3. In response to Sunovion's charges of patent infringement, Teva has alleged certain defenses and counterclaims, including that the Sunovion Patents are invalid. No

decision has been obtained by the parties from this Court regarding these charges of in fringement or these defenses and counterclaims.

- 4. Teva has not rebutted the statutory presumption that the Sunovion Patents are valid and enforceable in the Litigation. This admission is without prejudice to Teva's defenses and counterclaims that the Sunovion Patents are invalid.
- 5. Teva admits that the submission of ANDA No. 91-169 containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of generic tablets containing 1, 2, and 3 milligrams of eszopiclone per tablet within the United States before the expiration of the Sunovion Patents was a technical act of infringement of the Sunovion Patents under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to Teva's defenses and counterclaims that the Sunovion Patents are invalid.
- 6. All claims, counterclaims, and affirmative defenses presented by Sunovion as between it and Teva or by Teva in the Litigation are hereby dismissed without prejudice.
- 7. Teva, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, shall not engage in manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic tablet product containing 1, 2, and/or 3 milligrams of eszopiclone per tablet that is the subject of ANDA No. 91-169 until:
- (a) the expiration date of U.S. Patent 6,444,673 ("the '673 patent") including a patent term extension pursuant to 35 U.S.C. § 156, minus two and one half months (i.e., November 30, 2013);
- (b) in the event that prior to November 30, 2013, the FDA grants pediatric exclusivity for Lunesta®, the expiration date of the '673 patent, including a patent term extension pursuant to 35 U.S.C. § 156, and extended by six months by pediatric exclusivity pursuant to 21 U.S.C. § 355a, minus two and one half months (i.e., May 31, 2014); or

- (c) at such earlier date as may be permitted by the Settlement and License Agreement that the Parties have entered into.
- 8. Sunovion and Teva each expressly waives any right to appeal or otherwise move for relief from this Consent Judgment and Dismissal Order.
- 9. This court retains jurisdiction over Sunovion and Teva for purposes of enforcing this Consent Judgment and Dismissal Order.
  - 10. The Clerk of the Court is directed to enter this Consent Judgment and

Dismissal Order forthwith.

IT IS SO STIPULATED:

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SO ORDERED:

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SU UKDEKED:

HONORABLE DENNIS M. CAVAN LUGH

UNITED STATES DISTRICT JUDGE